causing drug-induced hepatotoxicity in an individual to a level and without causing drug-induced elevations in uric acid or glucose or both to levels which would require use of the intermediate release nicotinic acid formulation to be discontinued by the individual, comprising

orally administering to the individual once-a-day as a single dose an effective amount of an intermediate release nicotinic acid formulation without causing drug-induced hepatotoxicity in the individual to a level and without causing drug-induced elevations in uric acid or glucose or both to levels which would require use of the intermediate release nicotinic acid formulation by the individual to be discontinued, the intermediate release nicotinic acid formulation having

a dissolution curve similarity fit factor F_2 of at least about 79, and

an *in vitro* dissolution profile, when measured in a type I dissolution apparatus (basket), according to U.S. Pharmacopeia XXII, at about 37°C in deionized water at about 100 rpm, as follows

(a) less than about 15% of the nicotinic acid is released after about 1 hour in the apparatus,

(b) between about 15% and 30% of the nicotinic acid is released after about 3 hours in the apparatus,

(c) between about 30% and 45% of the nicotinic acid is released after about 6 hours in the apparatus,

(d) between about 40% and 60% of the nicotinic acid is released after about 9 hours in the apparatus,

(e) between about 50% and 75% of the nicotinic acid is released after about12 hours in the apparatus,

(f) at least about 75% of the nicotinic acid is released after about 20 hours in the apparatus.

(16)(AMENDED) A method of treating a lipidemic disorder with [a] an intermediate release nicotinic acid formulation suitable for oral administration once-a-day as a single dose without causing drug-induced hepatotoxicity in an individual to a level and without causing drug-induced elevations in uric acid or glucose or both to levels which would require use of the intermediate

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release nicotinic acid formulation to be discontinued by the individual, comprising

orally administering to the individual once-a-day as a single dose an effective amount of an intermediate release nicotinic acid formulation without causing drug-induced hepatotoxicity in the individual to a level and without causing drug-induced elevations in uric acid or glucose or both to levels which would require use of the intermediate release nicotinic acid formulation by the individual to be discontinued, the intermediate release nicotinic acid formulation containing at least about 1000 mg of nicotinic acid and having

a dissolution curve similarity fit factor F_2 of at least about 44, and

an *in vitro* dissolution profile, when measured in a type I dissolution apparatus (basket), according to U.S. Pharmacopeia XXII, at about 37°C in deionized water at about 100 rpm, as follows

(a) less than about 15% of the nicotinic acid is released after about 1 hour in the apparatus,

(b) between about 15% and 30% of the nicotinic acid is released after about 3 hours in the apparatus,

(c) between about 30% and 45% of the nicotinic acid is released after about 6 hours in the apparatus,

(d) between about 40% and 60% of the nicotinic acid is released after about 9 hours in the apparatus,

(e) between about 50% and 75% of the nicotinic acid is released after about12 hours in the apparatus,

(f) at least about 75% of the nicotinic acid is released after about 20 hours in the apparatus.

Remarks

In the Amendment dated, March 30, 1999, amendments to claims 1 and 16 were proposed. The Examiner in the November 24, 1999 Office Action, however, did not enter the amendment on technicality, i.e., the proposed addition to the claims contained more than five words.

It is respectfully submitted that the claims, as now amended herein, overcome the